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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,447	08/20/2003	Ricky W. Purcell	18189 (27839-2513)	7982
45736 7590 07/08/2010 Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP 7700 Forsyth Boulevard Suite 1800 St. Louis, MO 63105				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
07/08/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary

Application No.

10/645,447

Applicant(s)

PURCELL, RICKY W.

Examiner

Isis A. Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-43, 46, 47 and 49-62 is/are pending in the application.
- 4a) Of the above claim(s) 32-39 and 49-62 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 40-43, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date 7/27/2009

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

The receipt is acknowledged of applicant's IDS filed 07/27/2010.

Claims 32-43, 46, 47, 49-62 are pending.

Claims 32-39, 49-62 are withdrawn from consideration as being drawn to nonelected invention with traverse in the reply filed on 02/07/2007.

Claims 40-43, 46, and 47 are included in the prosecution.

Terminal Disclaimer

1. The terminal disclaimer filed on 05/28/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of the copending US patent application No. 10/954,764 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Board Decision

2. The Board Decision on 04/01/2009 stated: "While device 10 of Westplate may be considered to be a container having at least one compartment 12, and first and second patches/packets 21 (FF2), the Examiner has not pointed out, and we do not find, where

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Westplate describes the patches/packets 21 and the wrap 16 being within the same compartment 12 of device 10 as depicted in Figure 1 or any other disclosure of Westplate." Based on this analysis the following rejection would be proper.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 42 recites the limitation "said third patch" in the second line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 40, 41, 43, 46, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Westplate (US 4,592,358, of record) in view of either Kanios et al. (US 6,905,016, currently listed on PTO 892) or Sudsina et al. (US 6,004,345, currently listed on PTO 892).

Applicant Claims

Applicant's claim 40 is directed to a system for providing therapy to a portion of a body, the system comprising: a container that includes at least one compartment; a first patch held by said container, wherein said first patch applies a first therapy to the portion of the body when said first patch engages the portion of the body; a second patch held by said container, wherein said second patch applies a second therapy to the portion of the body when said second patch engages the portion of the body, the second therapy being different than the first therapy; and a flexible wrap held by said container, the flexible wrap being adapted to secure at least one of said first patch and said second patch to the portion of the body, wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container.

Claim 41 is directed to third patch in the container. Claim 43 requires enclosure for the patches, and claims 46 and 47 require container or board as a holder. Claim 46 recites more than one first patch in the container. Claim 47 requires releasably attachment of the patches to the holder.

Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)

Westplate teaches therapeutic device (10) to treat injured parts of the body featuring a plurality of compartments (12) enclosing packets (12) containing therapeutic substances which may be a **refrigerant, which reads on endothermic patch, a heat releasing substance, which reads on exothermic patch, and a high density material or weighed packets of high density materials, which reads on third patch**, the device may be wrapped on various body portions using strap means (16) (abstract; col.2, lines 15-19; col.4, lines 20-40; col.5, lines 25-26). The packets slide easily into compartments of the device, which reads on holder as a container (col.3, lines 1-4). Packets reads on patches claimed by applicants because applicant disclosed patch as "packs, packages, inserts, buttons, and/or any other devices that is readily applied near an injured portion of the body to apply therapy", page 5, lines 11-12 of the present disclosure. The figures show holder that can read on board. The device comprises a plurality of compartments, but any number of compartments may actually be filled with cooling or heating packets or weights for any particular application. The reference teaches that cooling or heating packets are removable, i.e. releasably attached (col.3, lines 6-20). A therapeutic device may be used to cool or heat, simultaneously, two different, but spaced nearby body areas (col.3, lines 26-35). The device is wrapped around the bodily injury by strap means that encircle the therapeutic

device (col.5, lines 50-53). The device is flexible, and this implies that the strap is flexible so it can be wrapped around and encircles areas of the body (col.5, lines 1, 10).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Although the device taught by Westplate may be considered to be a container having at least one compartment 12, first and second patches/packets 21, and wrap 16, all being held by one device 10, as interpreted by the board, however, Westplate does not explicitly teach the patches/packets and the flexible wrap are all within the same compartment in a container.

Kanios teaches a device for stabilizing drugs in patches and transdermal devices prior to use by providing a packaging system for transdermal patches to prevent and control degradation reaction that can result from moisture contamination and environmental factors (abstract; col.4, lines 5-14). The package is in the form of container or box having reusable lid and loaded with multiple patches (figure 2, col.9, lines 42-50; col.10, lines 63-64). Figure 2 shows one compartment container.

Sudsina teaches kit comprising medicinal elements and a wrap, all packaged and stored in one container to be all conveniently available for use together (figure 2, col.3, lines 54-63). Figure 2 shows one compartment container.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide therapeutic device featuring a plurality of compartments enclosing packets containing therapeutic substances which may be a refrigerant, a heat releasing, or a high density material, and a wrap as taught by Westplate, and enclose the device containing the packets and the wrap in a container as taught by Kanios. One would have been motivated to do so because Kanios teaches that multiple patches can be packaged in one container to prevent and control degradation reaction that can result from moisture contamination and environmental factors. Further one would have been motivated to enclose the device containing the packets and the wrap taught by Westplate in the container taught by Sudsina because Sudsina teaches that medicinal elements and a wrap can be all packaged and stored in one container to be conveniently available for use together. One would reasonably achieved package for multiple patches providing different therapeutic effects in one container wherein the patches are protected against moisture and environmental factors during storage and conveniently available for use, all together when needed.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

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8. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Westplate in view of either Kanios et al. or Sudsina et al. as applied to claims 40, 41, 43, 46 and 47 above, and further in view of Zhang et al. (US 6,245,347, of record).

Applicant Claims

Applicant's claim 42 is directed a third patch in the device that is a topical analgesic patch.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combined teachings of Westplate with either Kanios or Sudsina are previously discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Westplate desired to treat injured part of the body and teaches third type of patch in the device, however, the reference does not explicitly teach an analgesic patch as claimed by claim 42.

Zhang teaches analgesic patch that can be advantageously administered along with exothermic heating or endothermic cooling means or devices to control the release and absorption of the analgesic according to the patient's need. The cooling or heating

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device can be applied directly to the skin and can be fixed by tape, adhesive or the like (abstract; col.5, lines 22-26; col.7, lines 35-39; col.8, lines 27-31; col.9, lines 18-31).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide device for providing therapy to part of the body comprising container containing three packets/patches to treat injured part of the body including exothermic packet, endothermic packet, and third packet to provide therapy to injured portion of the body as taught by the combination of Westplate with Kanios or Sudsina, and further add analgesic patch that advantageously accompanied with cooling or heating means as taught by Zhang. One would have been motivated to add the analgesic patch because Westplate desired to treat injured parts of the body that may need analgesia and because Zhang teaches that it is advantageously to administer the analgesic patch along with exothermic heating or endothermic cooling devices to control the release and absorption of the analgesic. One would reasonable expect providing therapeutic device to injured part of the body comprising container containing exothermic packet, endothermic packet, and analgesic patch, wherein the system provides relief of the discomfort of the injured area and further provides controlled delivery of analgesic drug from the analgesic patch to relieve the pain and discomfort of the patient.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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